UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF WEST VIRGINIA AT CHARLESTON

IN RE: ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS PRODUCTS LIABILITY LITIGATION

Master File No. 2:12-MD-02327
MDL No. 2327

JOSEPH R. GOODWIN
U.S. DISTRICT JUDGE

PLAINTIFFS' OPPOSITION TO DEFENDANT ETHICON, INC.'S MOTION TO EXCLUDE GENERAL-CAUSATION TESTIMONY OF DONALD R. OSTERGARD, M.D.

I. INTRODUCTION

Now come Plaintiffs in opposition to Defendant Ethicon, Inc.'s ("Ethicon") Motion to Exclude the General-Causation Testimony of Donald R. Ostergard, M.D. ("Dr. Ostergard") along with the Memorandum in support thereof ("Ethicon's Brief")[1] filed with this Court April 21, 2016. Dr. Ostergard's opinions are set forth in the Rule 26 Report of [Dr. Ostergard] dated January 31, 2016[2] and also in his deposition of March 9, 2016. ("Ostergard Deposition".)[3]

Ethicon seeks to exclude opinions of Dr. Ostergard that are clearly admissible including 1) his opinions regarding the degradation and toxicity of the polypropylene mesh ("mesh") which is the major component of the Ethicon products at issue before this Court;[4] 2) his opinions that mesh is defective, if and when, it is implanted transvaginally; 3) that meshes of lighter weight and/or

[1] Citations to Ethicon's Brief will be in the form ("Br. ___.").
[2] The Ostergard Report is attached hereto as Exhibit A. Cites to it will be in the form (Ex. A, ___).
[3] Relevant excerpts of the Ostergard Deposition are attached hereto as Exhibit B. Citations to it will be in the form Ex. B, __:__,__:__.).
[4] These products include the Prolift and Prolift t-M; Prolene, Gynemesh and Gynemesh PS, manufactured and marketed by Ethicon for the treatment of pelvic organ prolapse ("POP".).

that are less-stiff than those used by Ethicon in its products are preferable for use in POP surgeries; and 4) Dr. Ostergard's opinions that mesh is prone to cause infections. For the reasons set forth herein, those opinions should be admitted in full.

Finally, Ethicon argues that Dr. Ostergard's opinions regarding Ethicon's state of mind, ethics or corporate conduct, his alleged narrative review of Ethicon's documents, and his opinions regarding FDA regulatory requirements and warnings must be excluded. Plaintiffs recognize that this Court has limited similar testimony from medical experts previously. However, Ethicon's motion should be granted so as to limit or exclude any such opinions only insofar as they are of the same nature as those which the Court has previously excluded.[5]

II. LEGAL STANDARD

The task of evaluating the reliability of expert testimony is uniquely entrusted to the district court. *Daubert v. Merrell Dow Pharmaceuticals, Inc*. 509 U.S. 579, 589 (1993). District courts enjoy "considerable leeway" in determining the admissibility of expert testimony. *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 152 (1999). A trial judge's decision to admit expert testimony is reviewed only for an abuse of discretion, and reviewing courts will not find an abuse unless a ruling is "arbitrary and irrational." *United States v. Cloud*, 680 F.3d 396, 401 (4th Cir. 2012); *Cavallo v. Star Ent.*, 100 F.3d 1150, 1153 (4th Cir. 1996); *United States v. Dorsey*, 45 F.3d 809, 812 (4th Cir. 1995).

Under Federal Rule of Evidence ("Rule") 702, if scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a

[5] Ethicon seeks to exclude those opinions at pages 11-13 of the Ethicon Brief, (Br. 11-13.) Plaintiffs do not otherwise address Ethicon's arguments herein.

witness qualified[6] as an expert by knowledge, skill, experience, training, or education may testify thereto in the form of an opinion or otherwise, provided the testimony (1) is "based upon sufficient facts or data" and (2) is "the product of reliable principles and methods," (3) which have been reliably applied "to the facts of the case." *In re C.R. Bard, Inc.*, 948 F. Supp. 2d 589, 601 (S.D.W. Va. 2013). A two-part test governs the admissibility of expert testimony. The evidence is admitted if it "rests on a reliable foundation and is relevant." *Daubert v. Merrell Dow Pharm.*, 509 U.S. 579, 597, 113 S.Ct. 2786, 125 L.Ed.2d 469 (1993).

The testimony Dr. Ostergard seeks to proffer is in full compliance with the standards set forth in Rule 702, *Daubert*, and its progeny. *See* Rule 702; *see also Daubert*, 509 U.S. at 597 (to be admitted evidence must "rest [ ] on a reliable foundation and [be] relevant"); *Westberry v. Gislaved Gummi AB*, 178 F.3d 257, 262 (4th Cir. 1999) ("[T]he obligation of a district court to determine whether expert testimony is reliable and relevant applies to all expert testimony [i.e. scientific and non-scientific]."); *Davis v. U.S.*, C. A. No. 5:10-CV-00384, 2011 WL 7053628 at *2 (S.D.W. Va. September 16, 2011) (The court applied Rule 702/*Daubert* principles in deciding that the expert qualified as a Life Cycle Planner and that her methodologies were sufficiently reliable under law.). To the extent applicable, Dr. Ostergard's testimony is also within the bounds of Rule 104(a). *See* Rule 104(a). In addition, Plaintiffs aver that the law requires that Rule 702 be applied flexibly, *see Daubert*, 509 U.S. at 594, so as to uphold the general framework of the Rules which favors the admissibility of evidence over non-admissibility. *Id*. at 588. In short, "the rejection of expert testimony is the exception rather than the rule." *U.S. v. Stanley*, No. 12-4572, 2013 WL 3770713 at *1 (4th Cir. July 19, 2013) (internal quotations omitted in the cited

[6] Ethicon concedes that this Court has found Dr. Ostergard qualified to testify regarding polypropylene in several previous opinions and states specifically that it is not moving to exclude Dr. Ostergard on the ground of qualifications. (*See* Br. 2, n.2.)

quotation.). Plaintiffs respectfully move that the expert testimony proffered by Dr. Ostergard should be admitted in full and that Ethicon's motion should be denied.

III. LEGAL ARGUMENT

A. Dr. Ostergard's General Opinions That Mesh Degrades and is Toxic When Implanted in the Human Body Are Both Reliable and Relevant and Should Be Admitted.

By Ethicon's own admission, this Court has found previously that Dr. Ostergard's opinions regarding both mesh degradation and toxicity are admissible. (Br. 2)(citing to *Tyree v. Boston Sci. Corp.*, 54 F.Supp.3d 501, 551 (S.D.W. Va. 2014), as amended (October 29, 2014); *Hall v. Boston Sci. Corp.*, No. 2:12-CV-08186, 2015 WL 868907 at *22-23 (S.D.W. Va. February 27, 2015); *Wise v. C.R. Bard, Inc.*, No. 2:12-CV-01378, 2015 WL 521202 at *5-7 (S.D.W. Va. February 7, 2015). Now not content to live with those previous rulings of the Court, Ethicon seeks to exclude substantially the same opinions this Court ruled admissible in numerous other cases, but now for reasons ostensibly not previously considered by the Court. Ethicon's attempt to take a second bite of the same apple should not be countenanced and Dr. Ostergard's opinions regarding the toxicity of mesh and its tendency to degrade should be admitted in full. (Br. 2-3)(*see e.g.*, Ex. A, 3(d)(f), 5(o),[7] 6(u),[8] 7(b)(b).)

Ethicon argues that Dr. Ostergard's testimony on toxicity must be excluded because he cannot identify with specificity the chemicals that polypropylene mesh leaches into the human body when implanted. In support, Ethicon cites to this Court's exclusion of Dr. Abhay Pandit ("Dr. Pandit") in *Huskey*, 29 F.Supp.3d at 711, a case which is easily distinguished.

In *Huskey*, Dr. Pandit was offered as a biomedical engineer and not for general medical testimony, like Dr. Ostergard. *Id*. The Court found Dr. Pandit's testimony to be unreliable because

[7] Evidencing a high rate of cytotoxicity in polypropelene mesh in a clinical study Ethicon funded itself.
[8] *See* n.7.

he was called to offer opinion on the biochemical properties of the mesh, itself. *Id*. This is not true here where Dr. Ostergard is not being called to testify as to any specific chemical make-up of the mesh, but, rather, that the chemicals in polypropylene mesh, whatever they may be, cause severe and deleterious effects in the human body. This Court has found Dr. Ostergard's opinions regarding the "defective" qualities of mesh to be reliable and admissible on similar bases in previous mesh cases. *See Hall*, 2015 WL 868907 at *23 (holding Dr. Ostergard's opinions that mesh displayed defective qualities to be admissible even though he conducted no independent experimentation or testing to support his opinions. The Court held that Dr. Ostergard clearly supported his opinions with reliable sources including the testing and scholarship of others.). In addition, since Dr. Ostergard supports his opinions on chemical leaching with ample citation to reliable authorities based both on his own scholarship and that of others, any argument Ethicon now raises about his reliance materials goes to the weight that Ostergard's testimony should be given at trial and not to its admissibility at the *Daubert* phase. *See Id*. ("Here, Dr. Ostergard conducted a thorough review of other's medical research in establishing his opinions. Whether Dr. Ostergard correctly interpreted this research has no bearing on the admissibility of his opinions. Accordingly, **I FIND** that Dr. Ostergard's opinions on the properties of polypropylene are reliable.")(internal cites and parentheticals omitted.); (see also Ex. A, 8-31 and Exhibit B attached to the Ostergard Report .) In sum, whether or not Dr. Ostergard is capable of identifying the particular chemicals that leach from mesh[9] is utterly immaterial to the general opinions he seeks to proffer here that chemicals in polypropylene mesh leach when used in medical devices intend to be implanted in the human body, causing toxicity, and leading to many deleterious consequences

[9] Finding it irrelevant to the present analysis, Plaintiffs neither concede nor deny this point.

for the women who have the devices. Dr. Ostergard's opinions regarding the toxicity of mesh are reliable and should be admitted in full.

In a somewhat related point, Ethicon argues that Dr. Ostergard's opinions that mesh degrades and becomes toxic when implanted are irrelevant because he cannot link them to Plaintiffs' injuries. (Br. 4-6.) As a preliminary matter, Dr. Ostergard is offering general opinions in this case and, therefore, need not provide testimony related to specific causation in the cases presently before the Court. Rather, his opinions are relevant (i.e. meet *Daubert's* "fit requirement") (*see Daubert v. Merrell Dow Pharma, Inc.*, ("*Daubert* II"), 43 F.3d 1311, 1315 (9th Cir. 1995)) if they will advance Plaintiffs' general causation opinions that mesh can and does cause the types of injuries Plaintiffs have sustained. *See Edwards v. Ethicon*, C.A. No. 2:12-CV-09972, 2014 WL 3361923 at *5 (S.D.W. Va. July 8, 2014)(this Court denying defendant's motion to exclude a medical expert's general opinion, and finding defendant's arguments regarding a medical expert's alleged failure to link plaintiff's injuries to the expert's general opinion that mesh was defective should be raised at trial instead.)("Ethicon is incorrect that Dr. Steege's *general causation* testimony – that the TVT-O mesh can degrade, fray, or lose particles - - should be excluded under Rule 702 simply because the plaintiffs may fail to carry their burden as to *specific causation* that Ms. Edwards was injured by the TVT-O mesh.") Dr. Ostergard's testimony clearly meets this requirement. For example, he testifies that dyspareunia with an onset long after one would expect post-surgical pain to cease is directly-related to mesh's tendency to degrade:

> **[Dr. Ostergard testifying]** . . . with prolapse, because of the shrinkage of the mesh and the degradation of the mesh and excessive scar tissue that's formed, the dyspareunia can occur at a later date.

(Ex. B, 52:6-9)(supporting his opinion that the Prolift device leads to late-onset dyspareunia compared to native tissue repairs.).

In addition, at his deposition, Dr. Ostergard was asked very directly by Ethicon's counsel if he believed that the Prolift and Gynemesh PS were defective and why. (*Id*. 90:9-15.) In answering, Dr. Ostergard testified that mesh in those devices is defective because it degrades leading to health complications for the women receiving the devices including 1) mesh contraction with resulting pain; 2) mesh erosion, creating scar tissue and contraction in the vagina over time; 3) scarring so severe that sexual intercourse becomes impossible; and 4) chronic pain that may never be alleviated at all. (*Id*. 90:15-91:16.)

Dr. Ostergard supports his opinions regarding degradation with studies from other scientists, as allowed under *Daubert*. *See Hall*, 2015 WL 868907 at *23; (*see also* Ex. B, 100:6-15)(referencing research by pathologist, Dr. Iakovlev, showing mesh degradation in explants of devices manufactured by every manufacturer Dr. Iakovlev studied.). Dr. Ostergard also supports his opinions that mesh degrades by a study Ethicon developed, itself:

> . . . out of, I think, six different patients, Ethicon was able to show degradation in two or three of them and have photographs to prove it. I think that's a significant finding.

(*Id*. 99:22-100:1.)(*See supra*. n.7.)

And, most importantly, Dr. Ostergard amply supports his opinion that mesh degrades through his own wealth of clinical expertise as contemplated by Rule 702, itself, *see* Rule 702 (so long as the opinion is also based on sufficient factors or data, an expert may qualify by "knowledge, skill, experience, training or education"):

> **[Dr. Ostergard testifying]** The only time we are able to see this degradation, and I think this was mentioned in one of Ethicon's patients - - oh, it is attached to one of the expert reports, or is mentioned that on removal of the mesh, it fell apart. It fell apart, so all the mesh could not be taken out.
>
> And this has been my experience as well. The mesh frequently does that. You can't get it all out. And even Ethicon has likened this to rebar in concrete. You can't get the rebar out.

(Ex. B, 102:14-23.)

B. Dr. Ostergard's Opinion that Mesh is Defective When Used Transvaginally is Fully Consistent with his Clinical Practice and Should Be Admitted in Full.

Ethicon argues that Dr. Ostergard's opinions that mesh, when used transvaginally, is defective is inconsistent with his clinical practice. (Br. 6.) This is not true. In fact, Dr. Ostergard testified repeatedly during his deposition that he used transvaginal mesh only sparingly in his clinical practice and, then, only implanting some polypropylene slings for the treatment of stress urinary incontinence. (*See* Ex. B, 33:19-35:10; 38:24-39:17.) Dr. Ostergard never used the Prolift device at all in practice; (*id*. 22:18-20), never used transvaginal mesh for prolapse repairs; (*id*. 139:10-16) (testifying that he only used mesh for abdominal repairs of prolapse); and even went so far as to eliminate prolene sutures from his surgeries. (*Id*. 112:20-113:17.) Dr. Ostergard's opinion that the placement of a mesh device violates a basic tenet of surgical teaching (Ex. A, 4)(see also Br. 7) is fully consistent with his clinical practice and is admissible.[10]

C. Dr. Ostergard's Opinions on Infection Are Admissible.

As a medical expert, Dr. Ostergard is well-qualified to offer opinions that mesh causes infection and he supports his opinion through his clinical experience. *See* Rule 702; *see also Edwards*, 2014 WL 3361923 at *11 (the Court accepting Ethicon's failure to challenge the reliability of the opinions of a medical expert that mesh can cause infections.). Plaintiffs plan to offer Dr. Ostergard's opinions on infection to the extent that the Wave I Plaintiffs allege conditions evidencing infection from their mesh devices. Even Ethicon concedes this is appropriate. (Br. 10-11.) In addition, Dr. Ostergard is presently offering ***general opinion testimony*** that mesh becomes

[10] That Dr. Ostergard trained fellows in the full-range of transvaginal procedures, including the use of mesh, (Br. 7-8), does nothing to change the fact that Dr. Ostergard limited the use of mesh in his practice where possible. At this point in time, a complete training of urological and gynecological surgeons requires that mesh repairs be taught. This does not alter that Dr. Ostergard believes mesh devices are defective, particularly when used transvaginally, or that he limited their use in his clinical practice.

infected, leading to health complications for women who have mesh implants. Dr. Ostergard's opinions should not be excluded now simply because Plaintiffs may not eventually be able to carry their burden as to specific causation at trial. *See Edwards*, 2014 WL 3361923 at *5.

IV. CONCLUSION

For reasons of the foregoing, the opinions of Dr. Ostergard should be admitted in full herein.

Date: May 9, 2016.

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CERTIFICATE OF SERVICE

I hereby certify that on May 9, 2016, I electronically filed the foregoing document with the Clerk of the court using CM/ECF system which will send notification of such filing to the CM/ECF participants registered to receive service in this MDL.

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